EXHIBIT J

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION THIS DOCUMENT RELATES TO WAVE 1	Master File No. 2:12-MD-02327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

RULE 26 EXPERT REPORT OF HOWARD JORDI, PhD

I, Dr. Howard Jordi have been asked to provide my expert opinion concerning the potential for Prolene polypropylene to undergo *in vivo* degradation. My opinions contained within this report relate to all of Ethicon's Prolene polypropylene mesh devices marketed for the treatment of pelvic organ prolapse and stress urinary incontinence, including Ethicon's Prolift, Prosima and TVT devices. I offer all opinions contained herein to a reasonable degree of scientific certainty or probability based on my extensive knowledge, training, education and experience, my thorough review of the relevant scientific publications concerning polypropylene degradation, my thorough review of Ethicon's internal documents and my analysis of data collected by me or at my direction using reliable scientific techniques recognized in the field of polymer science as reliable methods for the assessment of degradation of polymers generally and polypropylene specifically. I also rely on my prior Rule 26 Expert Reports served in the Lewis v. Ethicon and Bellew v. Ethicon matters.[1]

I. Background and Qualifications

I received my undergraduate degree in Chemistry from Northern Illinois University in 1967 and my Ph.D. in biochemistry from the same university in 1974.

From 1973-1977, I served in the United States Army Institute of Dental Research where I characterized various drugs contained in biodegradable copolymers of polylactic and polyglycolic acid. I then worked at Water's Associates from 1977-1980. Water's is a world leader in the sale of a wide range of analytical technologies including liquid chromatography, mass spectrometry, rheometry and microcalorimetry. At Waters, I progressed from a Biological Applications chemist to the laboratory manager for the life science division and finally to the Chemicals Applications Manager for the Chromatography Supplies Division.

[1] Lewis v. Ethicon, et al. Rule 26 Expert Report attached as Exhibit A; Bellew v. Ethicon, et al. Rule 26 Expert Report attached as Exhibit B.

Figure 4- SEM comparison between intact and degraded explants.[49]

In 2013, Wood *et al.*[50] published their data from their analysis of an explanted polypropylene mesh device. Using Scanning Electron Microscopy, these scientists found that the explanted polypropylene mesh fibers (d below) were cracked while the pristine, unused polypropylene fibers of the same product (a below) were smooth:

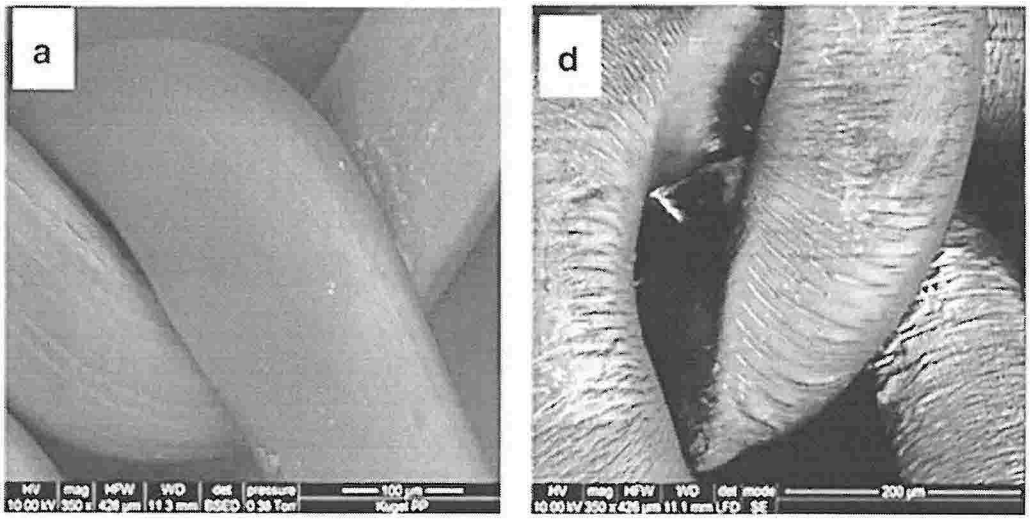

Figure 5- SEM images of pristine (a) polypropylene hernia mesh as well as explanted (d) polypropylene hernia mesh.[51]

To determine why the polypropylene had cracked, these scientists used FTIR. Wood *et al.* concluded that the cracked surface of the explanted polypropylene mesh was caused by oxidative degradation as confirmed by the presence of a carbonyl band at ~1740 cm^{-1}:

[49] Figures adapted from Arnaud Clave, Hanna Yahi, Jean-Claude Hammou, Suzelei Montanari, Pierre Gounon and Henri Clave, Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants, International Urogynecology Journal and Pelvic Floor Dysfunction 21 (2010) 261-270.

[50] A.J. Wood et al., Materials characterization and histological analysis of explanted polypropylene, PTFE, and PET hernia meshes from an individual patient, J. Mater Sci: Mater Med (2013) 24:1113-1122

[51] Figures adapted from A.J. Wood et al., Materials characterization and histological analysis of explanted polypropylene, PTFE, and PET hernia meshes from an individual patient, J. Mater Sci: Mater Med (2013) 24:1113-1122

Thus, for more than 50 years scientists who have studied polypropylene degradation have all reached the same conclusion: that polypropylene can degrade through the oxidation and/or environmental stress cracking pathways in the human body. Based on my knowledge, training and experience, my review of the scientific literature, and my review of Ethicon's own internal documents discussed below, it is my opinion to a reasonable degree of scientific certainty that polypropylene, including Ethicon's Prolene mesh device will degrade while implanted in the human body.

IV. Ethicon's Internal Documents Demonstrate that the Prolene Used in Ethicon's Products Undergoes *in vivo* Degradation

My review of Ethicon's internal documents provides additional support for my opinions and findings herein. Ethicon has conducted a number of studies confirming that Prolene degrades *in vivo*.

In 1985, Ethicon started a 10-year dog study that looked at the *in vivo* stability of various polymeric sutures, including Prolene and PVDF. The scientists internally published data from the 10-year dog study at the 2 year, 5 year, 6 year 10.5 months, and 7 year intervals. The data from the 10 year interval was not published because the dogs died prematurely.

On August 10, 1990, Ethicon scientists issued an internal report of their 5-year data from the 10-year dog study.[53] In that report, Ethicon's scientists concluded that "After 5 years *in* vivo the PVDF 5-0 suture was the only explanted material from five dogs which did not show any surface damage due to degradation. Out of seven PROLENE explants, two revealed cracking....The PROLENE surface, intact at the two year point, showed signs of degradation at five years."

The cracking observed on polypropylene is not a formaldehyde protein polymer, as has been previously argued by Ethicon's experts, as formalin was not used in Ethicon's dog study yet cracking was still observed. Moreover, Ethicon's scientists ruled out sample preparation as the cause for the cracking: "It can be said unequivocally that the cracking that was seen in any of the sutures was not introduced by sample preparation, i.e., drying. If cracking was observed on a dry suture in the light microscope or in the SEM, the same cracking was also found on the same suture after it had been in body fluids and then in sterile water, without ever having dried."

On May 29, 1992, Ethicon's scientists issued an internal report of the 10-year dog study after 6 years and 10 months.[54] Ethicon's scientists concluded that "[t]he only explanted suture still undamaged after 6 years and 10.5 months in vivo is the 5-0 PVDF suture" while "[a]ppoximately 50% of the PROLENE suture surface was cracked due to degradation."

On October 15, 1992, Ethicon's scientists issued an internal report of their 7-year data from the 10-year dog study.[55] Ethicon's scientist reported that "IR spectra of the cracked PROLENE specimens (Figure A) showed possible evidence of slight oxidation (a broadened weak

[53] ETH.MESH.11336474
[54] ETH.MESH.09888100
[55] ETH.MESH.09888187

absorbance at about 1650 cm^{-1}) and concluded "[d]egradation in PROLENE is still increasing and PVDF, even though a few cracks were found, is still by far the most surface resistant in-house made suture in terms of cracking."

The 1650 cm^{-1} and 1540 cm^{-1} bands are typically indicative of what are known as the amide-I and amide-II bands respectively of the polyamides.[56] Since proteins are polyamides, they should contain BOTH bands.

It is my opinion to a reasonable degree of scientific certainty that polypropylene mesh placed in the pelvic region of a woman's body will undergo greater degradation than polypropylene placed in the heart of a dog. Numerous studies in the scientific literature discuss the highly-septic, bacteria laden environment of the pelvis and specifically, the vagina.[57] Moreover, the higher surface area in Ethicon's Prolene polypropylene devices leads to greater foreign body reaction, greater inflammatory response and thus, higher amounts of inflammatory mediators attacking the surface of the fibers leading to greater amounts of degradation and oxidation.

While data in the 7 year dog study showed little to no macro molecular weight (Mw) loss, this is not evidence that the Prolene does not degrade. This is likely due to the solubilization of the total sample when only the surface polymer (as shown by SEM images) was in fact degraded. This behavior demonstrates that degradation starts on the surface and is not necessarily a bulk phenomenon. This would be expected as macrophages attack the exposed surface of the polypropylene material.[58] Therefore, even if no gross Mw degradation was observed, it cannot be stated to a reasonable degree of scientific certainty that the polypropylene suture did not degrade.

In fact, in my own experience analyzing explanted polypropylene devices manufactured by Ethicon using Nanothermal analysis, it was clearly shown that there was a vast difference between the melt temperatures at the surface of the explanted Prolene device (121-127 °C) compared to that of the exemplar (176 °C). It is known in the literature that the melt point of a polymer decreases with decreasing molecular weight.[59] It was shown using AFM that the depth of the surface cracking was ~ 1 um. In other words, the dissolution of non-cracked

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[56] The Infrared Spectra Atlas of Monomers and Polymers, Sadtler Research Laborataories, Philadelphia, PA 1983, page 471.

[57] Shah, K., Nikolavsky D., Flynn, B. Bacterialogical Analysis of Explanted Transvaginal Meshes, Infections/Inflammation of the Genitourinary Tract: Kidney & Bladder (II); 2013. http://www.aua2013.org/abstracts/archive/abstracts_MP42.cfm; Boulanger L, Boukerrou M, Rubod C, Collinet P, Fruchard A, Courcol RJ, Cosson M. Bacteriological analysis of meshes removed for complications after surgical management of urinary incontinence or pelvic organ prolapse. Int Urogynecol J Pelvic Floor Dysfunct. 2008 Jun;19(6):827-31; A. Vollebregt, A. Troelstra, and C. H. van der Vaart, Bacterial colonisation of collagen-coated polypropylene vaginal mesh: are additional intraoperative sterility procedures useful?, International urogynecology journal and pelvic floor dysfunction, vol. 20, no. 11, pp. 1345–51, Nov. 2009; Berrocal J., Clave H., Cosson M., Debodinance Ph., Garbin O., Jacquetin B., Rosenthal C., Salet-Lizee D., Villet R., Conceptual advances in the surgical management of genital prolapse The TVM Technique; J GynecolObestet Biol Reprod (2004) 33, 577-587; Choi, J et al., Use of Mesh During Ventral Hernia Repair in Clean-Contaminated and Contaminated Cases, Annals of Surgery (2012) 255:1

[58] S. A. M. Ali, S. -P. Zhong, P. J. Doherty and D. F. WIlliams, Biomaterials 14 (1993) 648-656.

[59] G. Natta, I. Pasquon, A. Zambelli and G. Gatti "Dependence of the melting point of isotactic polypropylenes on their molecular weight and degree of stereospecificity of different catalytic systems" Macromol. Chem. Phys.70 (1964) 191-205.

VII. COMPENSATION

I am compensated for investigation, study and consultation in this case at the rate of $350.00 per hour.

This 1st day of February, 2016

Howard Jordi, Ph.D.